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## SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

of

(Use as many sheets as necessary)

Complete	Complete if Known					
Application Number	10/820,144					
Filing Date	April 8, 2004					
First Named Inventor	CHANG, Esther H.					
Art Unit	1632					
Examiner Name	Shin-Lin Chen					
Attorney Docket Number	2474.0070003/BJD/JKM					

			U.S. PATENT DO	OCUMENTS .	
Examiner	Examiner Cite Initials No.1	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines,
Initials	No.	Number-Kind Code <sup>2 (If Known)</sup>	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear
ZM.	USI	5,108,921	04/28/1992	Low et al.	
1	US2	5,139,941	08/18/1992	Muzyczka et al.	
	US3	5,288,641	02/22/1994	Roizman	
	US4	5,378,457	01/03/1995	Paoletti et al.	
	US5	5,416,016	05/16/1995	Low et al.	
	US6	5,521,291	05/28/1996	Curiel et al.	
1	US7	5,547,932	08/20/1996	Curiel et al.	
	US8	5,635,382	06/03/1997	Low et al.	
	US9	5,762,938	06/09/1998	Paoletti et al.	
41	US10	5,833,975	11/10/1998	Paoletti et al.	
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Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>1</sup> Number <sup>2</sup> Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	т°
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Substitute for	form 1449/P	то		Complete if Known		
OFOON			-	Application Number	10/820,144	
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE				Filing Date	April 8, 2004	
				First Named Inventor	CHANG, Esther H.	
STATEMENT BY APPLICANT				Art Unit	1632	
	(Use as many sheets as necessary)		Examiner Name	Shin-Lin Chen		
Sheet	11	of	8	Attorney Docket Number	2474.0070003/BJD/JKM	

		NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²			
4v	NPL1	Alberts. B., et al., "The Receptors for Most Growth Factors are Transmembrane Tyrosine-Specific Protein Kinases." Chapter 15: Cell Signaling in Molecular Biology of the Cell, Robertson, M., and Adams, R., eds., Grandland Publishing, New York, NY. P. 760 (1994)				
1	NPL2	Aisen, P., "Transferrin, the Transferrin Receptor, and the Uptake of Iron by Cells," <i>Met. Ions Biol. Syst.</i> 35:585-631, Dekker. (1998)				
	NPL3	Antony, A.C., et al., "Folate Receptors," Annu. Rev. Nutr. 16:501-521, Annual Reviews Inc. (1996)				
	NPL4	Asagari, K., et al., "Inhibition of the Growth of Pre-Established Subcutaneous Tumor Nodules of Human Prostate Cancer Cells by Single Injection of the Recombinant Adenovirus p53 Expression Vector," Int. J. Cancer 71:377-382, Wiley-Liss, Inc. (1997)				
	NPL5	Awan, A.M., et al., "Recent Advances in Radiation Therapy for Head and Neck Cancer," Hematol. Oncol. Clin. North Am. 5:635-655, W.B. Saunders Company (1991)				
	NPL6	Baselga, J. and Mendelsohn, J., "Receptor Blockade with Monoclonal Antibodies as Anti-Cancer Therapy," <i>Pharmac. Ther.</i> 64:127-154, Elsevier Science Ltd. (1994)				
	NPL7	Berkner, K.L., "Development of Adenovirus Vector for the Expression of Heterologous Genes," <i>Biotechniques</i> 6:616-628, Eaton Publishing Co., (1988)				
	NPL8	Bischoff, J.R. et al., "An Adenovirus Mutant That Replicates Selectively in p53- Deficient Human Tumor Cells," Science 274:373-376, American Association for the Advancement of Science (1996)				
	NPL9	Brachman, D.G., "Molecular Biology of Head and Neck Cancer," Semin. Oncol. 21:320-329, W.B. Saunders Company (1994)				
ln	NPL10	Bristow, R.G., et al., "The p53 gene as a modifier of intrinsic radiosensitivity: implications for radiotherapy," Radiother. Oncol. 40:197-223, Elsevier Science Ireland Ltd. (1996)				
Examiner Signature		Solle Date Considered (2-12-07)				

Signature Considered Considered Considered \*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of Information is required by 37 CFR 1.98. The Information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute fo	Substitute for form 1449/PTO				Com	Complete if Known			
05001		100		NITAL	Application Number	10/820,144			
SECOND SUPPLEMENTAL					Filing Date	April 8, 2004			
INFORMATION DISCLOSURE				First Named Inventor	CHANG, Esther H.				
STATEMENT BY APPLICANT		Art Unit	1632						
(Use as many sheets as necessary)			sheets as	necessary)	Examiner Name	Shin-Lin Chen			
Sheet		2	of	8	Attorney Docket Number	2474.0070003/ВЈД/ЈКМ			
4	NPL		Liposo	me-Mediated	otor Ligand-Facilated Gene Transfer: Enhancement of Gene Transfer and Expression by Transferrin," Hum. Gene ry Ann Liebert, Inc. (1996)				

Examiner	611/10	Date	12-12-27
Signature		Considered	

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Substitute for	form 1449/P	то		Con	Complete if Known		
OF CON			-	Application Number	10/820,144		
SECON				Filing Date	April 8, 2004		
INFORMATION DISCLOSURE				First Named Inventor	CHANG, Esther H.		
STATEMENT BY APPLICANT				Art Unit	1632		
(Use as many sheets as necessary)		Examiner Name	Shin-Lin Chen				
Sheet	3	of	8	Attorney Docket Number	2474.0070003/BJD/JKM		

•		Non Patent Literature Documents	
Examiner Initials No. NPL12		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
		Clayman, G.L., et al., "In Vivo Molecular Therapy with p53 Adenovirus for Microscopic Residual Head and Neck Squamous Carcinoma," Cancer Res. 55:1-6, American Association for Cancer Research (1995)	
	NPL13	Cotten, M., et al., "High-efficiency receptor-mediated delivery of small and large 48 kilobase gene constructs using the endosome-disruption activity of defective or chemically inactivated adenovirus particles," <i>Proc. Natl. Acad. Sci. USA</i> 89:6094-6098, The National Academy of Sciences (1992)	
	NPL14	Couffinhal, T., et al., "Histochemical Staining Following LacZ Gene Transfer Underestimates Transfection Efficiency," Hum. Gene Ther. 8:929-934, Mary Ann Liebert, Inc. (1997)	
	NPL15	Cristiano, R.J. and Curiel, D.T., et al., "Strategies to accomplish gene delivery via the receptor-mediated endocytosis pathway," Cancer Gene Ther. 3:49-57, American Association for Cancer Research (1996)	
	NPL16	Dimery, I.W. and Hong, W.K., "Overview of Combined Modality Therapies for Head and Neck Cancer," J. Natl. Cancer Inst. 85:95-111, Oxford University Press (1993)	
	NPL17	Dorr, F.A., "Antisense Oligonucleotides in the Treatment of Cancer," Antisense Nucleic Acid Drug Dev. 9:391-396, Mary Ann Liebert, Inc. (1999)	
	NPL18	Douglas, J.T., et al., "Targeted gene delivery by tropism-modified adenoviral vectors," Nat. Biotech. 14:1574-1578, Nature Publishing Group (1996)	
	NPL19	Farhood, H., et al., "Cationic liposomes for direct gene transfer in therapy of cancer and other diseases," Ann. N.Y. Acad. Sci. 716-23-34, New York Academy of Sciences (1994)	
Gu	NPL20	Felgner, P.L., et al., "Improved Cationic Lipid Formulations for In Vivo Gene Therapy," Ann. N.Y. Acad. Sci. 772:126-139, New York Academy of Sciences (1995)	

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Substitute for	form 1449/P1	ro		Com	Complete if Known		
CECON			ENTAL	Application Number	10/820,144		
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE				Filing Date	April 8, 2004		
				First Named Inventor	CHANG, Esther H.		
STATEMENT BY APPLICANT				Art Unit	1632		
(Use as many sheets as necessary)		Examiner Name	Shin-Lin Chen				
Sheet	4	of	8	Attorney Docket Number	2474.0070003/BJD/JKM		

		Non Patent Literature Documents			
Examiner Cite Initials* No.1					
Gre	NPL21	Gottschalk, S., et al., "Folate receptor mediated DNA delivery into tumor cells: potosomal disruption results in enhanced gene expression," Gene Ther. 1:185-191, Nature Publishing Group (1994)			
	NPL22	Goud, B., et al., "Antibody-Mediated Binding of a Murine Ecotropic Moloney Retroviral Vector to Human Cells Allows Internalization But Not the Establishment of the Proviral State," Virol. 163:251-254, Academic Press, Inc. (1988)			
	NPL23	Hall, A.R., et al., "p53-dependent cell death/apoptosis is required for a productive adenovirus infection," Nat. Med. 4:1066-1072, Nature Publishing Company (1998)			
	NPL24	Harris, C.C., "p53 Tumor suppressor gene: from the basic research laboratory to the clinic-an abridged historical perspective," <i>Carcinogenesis 17</i> :1187-1198, Oxford University Press (1996)			
	NPL25	Heise, C., et al., "ONXY-015, an E1B gene-attenuated adenovirus, causes tumor-specific cytolysis and antitumoral efficacy that can be augmented by standard chemotherapeutic agents," Nat. Med. 3:639-645, Nature Publishing Group (1997)			
	NPL26	Hsiao, M., et al., "Intravavitary Liposome-Mediated p53 Gene Transfer into Glioblastoma with Endogenous Wild-Type p53 in Vivo Results in Tumor Suppression and Long-Term Survival," Biochem. Biophys. Res. Commun. 233:359-364, Academic Press (1997)			
	NPL27	Isaacs, W. B., et al., "Wile-Type p53 Suppresses Growth of Human Prostate Cancer Cells Containing Mutant p53 Alleles," Cancer Res. 51:4716-4720, American Association for Cancer Research (1991)			
	NPL28	Kastan, M.B., et al., "Participation of p53 Protein in the Cellular Response to DNA Damage," Cancer Res. 51:6304-6311, American Association for Cancer Research (1991)			
Lu	NPL29	Kataoka, M., et al., "An Agent That Increases Tumor Suppressor Transgene Product Coupled with Systemic Transgene Delivery Inhibits Growth of Metastatic Lung Cancer in Vivo," Cancer Res. 58:4761-4765, American Association for Cancer Research (1998)			

Examiner Signature	SM	ran	Date Considered	12-12-07

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Substitute for form 1449/PTO				Complete if Known		
05001	D 0110D		-NIT A 1	Application Number	10/820,144	
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE				Filing Date	April 8, 2004	
				First Named Inventor	CHANG, Esther H.	
STATEMENT BY APPLICANT				Art Unit	1632	
(Use as many sheets as necessary)				Examiner Name	Shin-Lin Chen	
Sheet	5	of	8	Attorney Docket Number	2474.0070003/ВJD/JKM	

			Non Patent Literature Documents	
Examiner Initials* Cite No.1  White No.1  NPL30				
		NPL30	Kirn, D., et al., "ONYX-015: Clinical data are encouraging," Nat. Med. 4:1341-1342, Nature America Inc. (1998)	
		NPL31	Kuerbitz, S.J., et al., "Wild-type p53 is a cell cycle checkpoint determinant following irradiation," Proc. Natl. Acad. Sci. USA 89: 7491-7495, The National Academy of Sciences (1992)	
		NPL32	Lee, R.J. and Low, P.S., "Delivery of Liposome into Cultured KB Cells via Folate Receptor-mediated Endocytosis," <i>J. Biol. Chem. 269</i> :3198-3204, The American Society for Biochemistry and Molecular Biology, Inc. (1994)	
		NPL33	Lee, R.J. and Low, P.S., et al., "Folate-mediated tumor cell targeting of liposome-entrapped doxorubicin in vitro," <i>Biochim. Biophys. Acta 1233</i> :134-144, Elsevier Science B.V. (1995)	
		NPL34	Lee, J.M. and Bernstein, A., "p53 mutations increase resistance to ionizing radiation," <i>Proc. Natl. Acad. Sci. USA 90</i> : 5742-5746, The National Academy of Sciences (1993)	
		NPL35	Lee, R.J. and Huang, R., "Folate-targeted, Anionic Liposome-entrapped Polylysine-condensed DNA for Tumor Cell-specific Gene Transfer," J. Biol. Chem. 271:8481-8487, The American Society for Biochemistry and Molecular Biology, Inc. (1996)	
		NPL36	Lewis, J.G., et al., "A serum-resistant cytofectin for cellular delivery of antisense oligodeoxynucleotides and plasmid DNA," Proc. Natl. Acad. Sci. USA 93:3176-3181, The National Academy of Sciences (1996)	
1		NPL37	Linke, S.P., "Has the smart bomb been defused," <i>Nature 395</i> :13 &15, Macmillan Publisher Ltd. (1998)	
4	n	NPL38	Lowe, S.W., et al:, "p53-Dependent Apoptosis Modulates the Cytotoxicity of Anticancer Agents," Cell 74:957-967, Cell Press (1993)	

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Signature	5000	Considered	12-12-01

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te for form 1449/PTO	Complete if Known						

## Substitute Application Number 10/820,144 SECOND SUPPLEMENTAL Filing Date April 8, 2004 INFORMATION DISCLOSURE First Named Inventor CHANG, Esther H. STATEMENT BY APPLICANT Art Unit 1632 (Use as many sheets as necessary) **Examiner Name** Shin-Lin Chen Attorney Docket Number 2474.0070003/BJD/JKM Sheet 6 of

		Non Patent Literature Documents	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T²
yu NPL3		Miyamoto, T., et al., "Transferrin receptor in oral tumors," Intl. J. Oral Maxillofac. Surg. 23:430-433, Munksgaard (1994)	
	NPL40	McIlwarth, A.J., et al., "Cell Cycle Arrests and Radiosenstivity of Human Tumor Cell Lines: Dependence on Wild-Type p53 for Radiosensitivity," Cancer Res. 54:3718-3722, American Association for Cancer Research (1994)	
	NPL41	O'Connor, P.M., et al., "Role of the p53 Tumor Supressor Gene in Cell Cycle Arrest and Radiosensitivity of Burkitt's Lymphoma Cell Lines, " Cancer Res. 53:4776-4780, American Association for Cancer Research (1993)	
	NPL42	Pitts, J.D., "Cancer Gene Therapy: A Bystander Effect Using the Gap Junctional Pathway," Mol. Carcinog. 11:217-130, Wiley-Liss, Inc. (1994)	
	NPL43	Prillo, K.F., "p53 mediated sensitization of squamous cell carcinoma of the head and neck to radiotherapy," <i>Oncogene 14</i> :1735-1746, Stockton Press (1997)	
	NPL44	Rogers, B.E., et al., "Use of a novel cross-linking method to nodify adenovirus tropism," Gene Ther. 4:1387-1392, Stockton Press (1997)	
	NPL45	Roux, P., et al., "A versatile and potentially general approach to the targeting of specific cell types by retroviruses: Application to the infection of human cells by means of major histocompatibility complex class I and class II antigens by mouse ecotropic murine leukemia virus-derived viruses," Proc. Natl. Acad. Sci. USA 86:9079-9083, The National Academy of Sciences (1989)	
GN	NPL46	Schwarzenberger, P., et al., "Receptor-Targeted Recombinant Adenovirus Conglomerates: a Novel Molecular Conjugate Vector with Improved Expression Characteristics," J. Virol 71:8563-8571, American Society for Microbiology (1997)	

Examiner Signature	Sollien	Date Considered	12-12-07
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Substitute for	form 1449/P	го		Con	Complete if Known		
CECON	0 01100		TAITAI	Application Number	10/820,144		
SECOND SUPPLEMENTAL INFORMATION DISCLOSURE				Filing Date	April 8, 2004		
				First Named Inventor	CHANG, Esther H.		
STATEMENT BY APPLICANT				Art Unit	1632		
	(Use as many	sheets a	s necessary)	Examiner Name	Shin-Lin Chen		
Sheet	7	of	8	Attorney Docket Number	2474.0070003/BJD/JKM		

	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T²			
w	NPL47	Seachrist, L., "Successful Gene Therapy Has Researchers Looking for the Bystander Effect," J. Natl. Cancer Inst. 86:82-83, Oxford University Press (1994)				
	NPL48	Selivanova, G., et al., "Mutant p53: The loaded gun," Curr Opin Investig Drugs 2:1136-1141, PharmaPress Ltd (2001)				
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	NPL51	Singh, M. "Transferring as a Targeting Ligand for Liposome and Anticancer Drugs," Curr. Pharm. Des. 5:443-451, Bentham Science Publishers B.V. (1999)				
	NPL52	Snitkovsky, S. and Young, A.T.J., et al., "Cell-specific viral targeting mediated by a soluble retroviral receptor-ligand fusion protein," Proc. Natl. Acad. Sci. USA 95:7063-7068, The National Academy of Sciences (1998)				
	NPL53	Srivastava, S., et al., "Germ-line transmission of a mutated p53 gene in a cancer- prone family with Li-Fraumeni syndrome," <i>Nature 348:747-749</i> , Nature Publishing Company (1997)				
	NPL54	Thorstensen, K. and Romslo, I., "The transferrin receptor: its diagnostic value and its potential as therapeutic target," Scand J. Clin. Lab. Investig. Suppl. 215:113-120, Universitetsforlaget (1993)				
	NPL55	Wagner, E., et al., "Coupling of adenovirus to transferrin-polylysine/DNA complexes greatly enhances receptor-mediated gene delivery and expression of transfected genes," Proc. Natl. Acad. Sci USA 89:6099-6103, The National Academy of Sciences (1992)				
4U	NPL56	Walker J.R., et al., "Local and Systemic Therapy of Human Prostate Adenocarcinoma with the Conditionally Replicating Herpes Simplex Virus Vector G207," Hum. Gene Ther. 10:2237-2243, Mary Ann Liebert, Inc. (1999)				

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SECOND SUPPLEMENTAL INFORMATION DISCLOSURE				Filing Date	April 8, 2004	
				First Named Inventor	CHANG, Esther H.	
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(Use as many sheets as necessary)			s necessary)	Examiner Name	Shin-Lin Chen	
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4u	NPL57	Weichselbaum, R.R., et al., "Radioresistant Tumor Cells are Present in Head and Neck Carcinomas That Recur After Radiotherapy," Int. J. Radiat.Oncol. Biol. Phys. 15:575-579, Pregamon Press (1988)	
	NPL58	Weivel, N.A. and Wilson, J.M., "Methods of Gene Delivery," Hematol. Oncol. Clin. North Am. 12:483-501, W.B. Saunders Company (1998)	
	NPL59	Xu, L., et al., "Systemic p53 gene therapy in combination with radiation results in human tumor regression," Tumor Targeting 4:92-104, Stockton Press (1999)	
	NPL60	Yang, C., et al., "Adenovirus-mediated Wild-Type p53 Expression Induces Apoptosis and Suppresses Tumorigenesis of Prostatic Tumor Cells," Cancer Res. 55:4210-4213, American Association for Cancer Research (1995)	
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gu	NPL62	O'Sullivan, M.J., et al., "Comparison of Two Methods of Preparing Enzyme- Antibody Conjugates: Application of these Conjugates for Enzyme Immunoassay," Anal. Biochem. 100:100-108, (1979)	
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